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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,778	10/21/2003	Jaymin C. Shah	PC25071A	4530

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PFIZER INC
150 EAST 42ND STREET
5TH FLOOR - STOP 49
NEW YORK, NY 10017-5612

EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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07/06/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/689,778	Applicant(s) SHAH, JAYMIN C.	
	Examiner James W. Rogers, Ph.D.	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

The amendments to the claims filed 06/08/2007 has been entered. Any objection/rejection not addressed in the office action below has been withdrawn.

Response to Arguments

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,3-11,13-14 and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (US 6,232,304 B1, cited by applicants) in view of Greengard et al. (US2003/0109419) and in view of Yuan et al. (US 5,594,141), for the reasons expressed in the office action dated 06/08/2007.

Applicant's arguments filed 06/08/2007 have been fully considered but they are not persuasive.

Applicants assert the examiner has trivialized the ingredients claimed by describing them as excipients and goes as far to state that the examiner has a complete misunderstanding of the important role of those elements. Applicants also assert that

the examiner has coupled the viscosity element with the optional surfactant and requests the examiner to decouple these elements in the rejection.

These assertions are unclear. The examiner stands by his characterization that the NaCMC and polysorbate are excipients, for evidence that these two elements are considered excipients by those of ordinary skill in the art applicants need to look no further than the cited Francois reference (US 2003/0157180) which at [0023] describes both NaCMC and TweenTM (polysorbate) as excipients. The examiner has obviously treated the two elements NaCMC (claimed as a viscosity agent) and polyoxyethylene sorbitan ester as two different elements since the examiner used two references to show these two elements individually (Greengard discloses polysorbate and Yuan discloses NaCMC). There is no need for the examiner to decouple two elements which he obviously thought were different enough to use two rejections to meet their limitations.

Applicants also claim to show unexpected results as shown in example 4, which purports to show comparative examples in which the formulation of applicants invention is compared to an immediate release formulation that comprised no viscosity agent as in Kim. The immediate release formulation was described by applicants as showing no depot effect, in other words there was no sustained serum concentration but applicants formulation did show a serum concentration after 48 hrs.

The assertion of unexpected results by applicants counsel is flawed. In order to show unexpected results the comparative example to applicant's invention must be the same. Example 4 compared 1) an immediate release formulation comprised of

solubilized ziprasidone and 2) an aqueous suspension comprised of a viscosity agent sulfobutyl ether- β -cyclodextrin (SBECD) and solubilized ziprasidone. Kim does not describe the same immediate release formulation as in 1) because Kim's invention requires a cyclodextrin (including SBECD) as part of the inclusion complexes of the aryl-heterocyclic salts. The examiner notes that it appears example 4, sample (2) may be describing the same invention disclosed in Kim, and thus applicant's counsel's arguments for unexpected results are misguided, flawed and non-persuasive.

Applicants assert that Greengard relates to optional surfactants and is therefore not relevant to patentability but applicants still argue that Greengard teaches away from the claimed invention because its list of formulation agents does not mention viscosity agents. Applicants also assert that the reference to surfactants is only made in the context of solid dosage forms.

The relevance of these assertions is unclear. Since the Greengard reference is used in a 103(a) type of rejection as a secondary reference it does not have to disclosed every element of applicants claimed invention. Greengard was used to show that the use of polysorbates in anti-psychotic drugs was already well known in the art at the time of the invention and was not used for a disclosure on viscosity agents, therefore applicants argument is moot. The assertion that Greengard only discloses surfactants for use in solid dosage forms is also unclear. Polysorbates are described as useful agents in the pharmaceutical compositions (which includes formulations for injection and parental administration) at [0397].

Applicants assert that Yuan's injectable formulations are regulated to a minor paragraph and there is no reference to solubilizing agents or viscosity agents.

The relevance of these assertions is unclear. Firstly the length of a disclosure does not preclude a teaching within a reference, Yuan does describe injectable formulations therefore Yuan discloses this element. Applicants seem to assert that because Yuan does not use the phrase "viscosity agent" to describe NaCMC it cannot meet the limitation of a viscosity agent, Yuan describes NaCMC as an excipient useful in aqueous suspensions, just because Yuan does not state it is a viscosity agent does not change the fact that the compound is the same and was disclosed as useful in aqueous formulations. The same compound will have the same properties and/or effects, therefore claiming another use of the same compound in a composition will not result in a patentable distinction. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established, Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable.

Claims 1,3-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (US 6,232,304 B1, cited by applicants) in view of Francois et al. (US 2003/0157180), for the reasons expressed in the office action dated 06/08/2007.

Applicants assert that Francois does not disclose the same active and turned to a metabolite of risperidone and further derivatized that material. Applicants assert that

because of the convoluted conversion of risperidone the reference teaches away from applicants claimed invention. Applicants further assert that nowhere in the reference does it mention of the phrase "viscosity agents".

The relevance of these assertions is unclear. Regarding applicant's assertion that Francois does not disclose the same active material and because of this the reference teaches away from the claimed invention, since the Francois reference is used in a 103(a) type of rejection as a secondary reference it does not have to disclosed each and every element of applicants claimed invention. Francois was used for the disclosure of NaCMC and polysorbate in injectable atypical anti-psychotic aryl-heterocycles were already well known in the art at the time of the invention and was not used for a disclosure on the exact active ingredient. Applicants seem to assert that because Francois does not use the phrase "viscosity agent" to describe NaCMC it cannot meet the limitation of a viscosity agent, Francois describes NaCMC as an excipient useful in depot formulations, just because Francois does not state it is a viscosity agent does not change the fact that the compound is the same and was disclosed as useful in depot formulations. The same compound will have the same properties and/or effects, therefore claiming another use of the same compound in a composition will not result in a patentable distinction. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established, Thus the claiming of a new use, new

function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable.

Lastly applicants assert that the examiner has provided only a disconnected patchwork of references that recite laundry list of ingredients and there would be no motivation for one of ordinary skill in the art to combine.

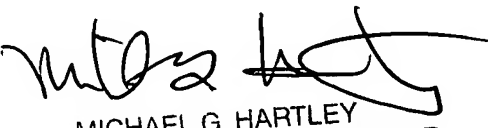
The examiner does not consider the disclosures of the secondary references above to describe laundry list of ingredients; all of the ingredients were expressed as useful in the inventions and would therefore be obvious for one of ordinary skill in the art to use in injectable anti-psychotic formulations. The motivation to combine the references was already described in the previous action and is incorporated bodily herein. Since the ingredients were all described as useful in injectable aqueous compositions containing an atypical anti-psychotic it would have been obvious to one skilled in the art to combine the ingredients described within the references to arrive at applicants claimed invention. The motivation for combining them flows from their having been used individually in the prior art, and from them being recognized in the prior art as useful for the same purpose.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER